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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/626,905
Filing Date	July 25, 2003
First Named Inventor	Franzoso, Guido
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	21459-94575

### ENCLOSURES (Check all that apply)

- |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br><input type="checkbox"/> Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance communication to Technology Center (TC)<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): |
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#### Remarks

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### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name

Alice O. Martin

Signature

*Alice O. Martin*

Date

*October 28, 2003*

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Date

*10/28/03*

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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B. J. P. & THORNBURG

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**PATENT APPLICATION  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Group Art  
Unit: Not Yet Assigned

Application No.: 10/626,905

Filing Date: July 25, 2003

First Named  
Inventor: Franzoso, Guido, *et al.*

Title: *METHODS AND COMPOSITIONS  
FOR MODULATING APOPTOSIS*

Attorney  
Docket No.: 21459-94575

Examiner  
Name: Not Yet Assigned

Certificate Under 37 CFR 1.8(a)

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on *October 28, 2003*

*Alice O. Martin*  
Alice O. Martin

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

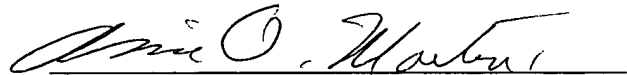
This statement is filed in the application identified above pursuant to 378 C.F.R. § 1.97 (b). No representation is intended that a complete search has been made of the prior art or that no better publications than listed on Forms PTO/SB/08A are available. A copy of the publications cited are not provided herewith for review by the Examiner as they were previously submitted to the Office for U.S. Ser. No. 10/263,330 on January 1, 2003 and June 30, 2003. If needed the applicants agent will gladly provide copies of these publications.

The filing of this Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in §1.56(b).

None of the cited publications are believed to disclose or suggest the invention recited in the claims of the above-identified application or the priority date of the application is before the publication date. It is therefore believed that the claimed invention is patentably distinguishable over these documents.

Please charge any fees that might be due in connection with this Information Disclosure Statement to our Deposit Account No. 12-0913 with reference to our attorney docket number (21459-94575).

Respectfully submitted,



Alice O. Martin  
Reg. No. 35,601

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Date:

October 28, 2013

FORM PTO/SB/08A  
(REV. 10-96)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

Substitute for form 3449A/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

Sheet 1 of 1

## Complete if Known

Application Number	10/ 263,330
Filing Date	October 2, 2002
First Named Inventor	FRANZOSO, Guido, <i>et al.</i>
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	21459-93823

**B OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>		T <sup>2</sup>
	B.1	DE SMAELE, Enrico, <i>et al.</i> (2001) "Induction of <i>gadd45</i> by NF- $\kappa$ B Downregulates Pro-apoptotic JNK Signaling." Letters to Nature. 414: 308-313.	
	B.2	DINKOVA-KOSTOVA, Albena T., <i>et al.</i> (2001) "Potency of Michael Reaction Acceptors as Inducers of Enzymes That Protect Against Carcinogenesis Depends on Their Reactivity With Sulfhydryl Groups." PNAS. 98: 3404-3409.	
	B.3	JIN, Ronguan, <i>et al.</i> (2002) "Regulation of the <i>gadd45</i> Promoter by NF- $\kappa$ B." DNA and Cell Biology. 21: 491-503.	
	B.4	PETER, Marcus E., <i>et al.</i> (1998) "Mechanisms of CD95 (APO-1/Fas)-mediated Apoptosis." Current Opinion in Immunology 10: 545-551.	
	B.5	RAMOS-GOMEZ, Minerva, <i>et al.</i> (2001) "Sensitivity to Carcinogenesis is Increased and Chemoprotective Efficacy of Enzyme Inducers is Lost in <i>nrf2</i> Transcription Factor-Deficient Mice." PNAS 98: 410-3415.	
	B.6	SCAFFIDI, Carsten, <i>et al.</i> (1998) "Two CD95 (APO-1/Fas) Signaling Pathways." The EMBO Journal. 17: 1675-1687.	
	B.7		
	B.8		
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	B.10		
	B.11		
	B.12		

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet 1 of 4

Complete if Known

Application Number:	10/ 263,330
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First Named Inventor:	FRANZOSO, Guido, <i>et al.</i>
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number:	21459-93823

## U.S. PATENT DOCUMENTS

*Examiner Initials	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A.1				
	A.2				
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	A.17				
	A.18				
	A.19				

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A.20	WO 84/03564	09-13-1984	GEYSEN, Hendrik <i>et al.</i>		
	A.21					
	A.22					
	A.23					
	A.24					

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet 2 of 4U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

## Complete if Known

Application Number	10/ 263,330
Filing Date	October 2, 2002
First Named Inventor	FRANZOSO, Guido, <i>et al.</i>
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	21459-93823

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>		T <sup>2</sup>
	A.1	Beg, Amer A. and Baltimore, David (1996) "An Essential Role for NF- $\kappa$ B in Preventing TNF- $\alpha$ -Induced Cell Death" <i>Science</i> 274 (5288):782.	
	A.2	Budihardjo, I., <i>et al.</i> (1999) "Biochemical Pathways of Caspase Activation During Apoptosis" <i>Annu. Rev. Cell Dev. Biol.</i> 15:269-90.	
	A.3	Chang, Lufen and Karin, Michael (2001) "Mammalian MAP Kinase Signalling Cascades" <i>Nature</i> 410(6824):37-40.	
	A.4	Davis, Roger J. (2000) "Signal Transduction by the JNK Group of MAP Kinases" <i>Cell</i> 103:239-252.	
	A.5	Franzoso, Guido, <i>et al.</i> (1992) "The Candidate Oncoprotein Bcl-3 is an Antagonist of p50/NF- $\kappa$ B-Mediated Inhibition" <i>Nature</i> 359:339-359.	
	A.6	Franzoso, Guido, <i>et al.</i> (2003) "JNK: A Killer on a Transcriptional Leash" <i>Cell Death and Differentiation</i> 10:13-15.	
	A.7	Gerlach, Wayne L., <i>et al.</i> (1987) "Construction of a Plant Disease Resistance Gene from the Satellite RNA of Tobacco Ringspot Virus" <i>Nature</i> 328:802-805.	
	A.8	Ghosh, Sankar, <i>et al.</i> (1998) "NF- $\kappa$ B and Rel Proteins: Evolutionarily Conserved Mediators of Immune Responses" <i>Annu. Rev. Immunol.</i> 16:225-60.	
	A.9	Guo, Yan-Lin, <i>et al.</i> (1998) "Correlation Between Sustained c-Jun N-terminal Protein Kinase Activation and Apoptosis Induced by Tumor Necrosis Factor- $\alpha$ in Rat Mesangial Cells" <i>The Journal of Biological Chemistry</i> 273, 13:4027-4034.	
	A.10	Heinemeyer, T., <i>et al.</i> (1999) "Expanding the TRANSFAC Database Towards an Expert System of Regulatory Molecular Mechanisms" <i>Nucleic Acids Research</i> 27, 1:318-322.	
	A.11	Huang, Shuang, <i>et al.</i> (1997) "Apoptosis Signaling Pathway in T Cells Is Composed of ICE/Ced-3 Family Proteases and MAP Kinase Kinase 6b" <i>Immunity</i> 6:739-749.	
	A.12	Johanson, Kyung, <i>et al.</i> (1995) "Binding Interactions of Human Interleukin 5 with Its Receptor $\alpha$ Subunit" <i>The Journal of Biological Chemistry</i> 270, 16:9459-9471.	

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet 3 of 4U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

Complete if Known

Application Number	10/ 263,330
Filing Date	October 2, 2002
First Named Inventor	FRANZOSO, Guido, <i>et al.</i>
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	21459-93823

## A OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>		T <sup>2</sup>
	B.1	Kim, Sung-Hou and Cech, Thomas R. (1987) "Three-Dimensional Model of the Active Site of the Self-Splicing rRNA Precursor of Tetrahymena" <i>Biochemistry</i> 84:8788-8792.	
	B.2	Lin, Anning, <i>et al.</i> (1995) "Identification of a Dual Specificity Kinase Activities the Jun Kinases and p38-Mpk" <i>Science</i> 268:286-290.	
	B.3	Liu, Zheng-gang, <i>et al.</i> (1996) "Dissection of TNF Receptor 1 Effector Functions: JNK Activation is Not Linked to Apoptosis While NF- $\kappa$ B Activation Prevents Cell Death" <i>Cell</i> 87:565-576.	
	B.4	Medema, Jan Paul, <i>et al.</i> (1997) "FLICE is Activated by Association with the CD95 Death-Inducing Signaling Complex (DISC)" <i>The EMBO Journal</i> 16, 10:2794-2804.	
	B.5	Michel, Francois and Westhof, Eric (1990) "Modelling of the Three-Dimensional Architecture of Group I Catalytic Introns Based on Comparative Sequence Analysis" <i>J. Mol. Biol.</i> 216:585-610.	
	B.6	Mitchell, M.S., <i>et al.</i> (1993) "Active Specific Immunotherapy of Melanoma with Allogeneic Cell Lysates. Rationale, Results, and Possible Mechanisms of Action" <i>Ann. N.Y. Acad Sci</i> 690,1: 153.-166.	
	B.7	Mitchell, Malcolm S., <i>et al.</i> (1990) "Active-Specific Immunotherapy for Melanoma" <i>Journal of Clinical Oncology</i> 8, 5: 856-869.	
	B.8	Morton, Bennett D., <i>et al.</i> (1995) "Kinetic Characterization of the Interaction of Biotinylated Human Interleukin 5 with an Fc Chimera of its Receptor Alpha Subunit and Development of an ELISA Screening Assay Using Real-Time Interaction Biosensor Analysis" <i>J. Mol. Recognit</i> 8, 1-2: 52-8.	
	B.9	Morton, Donald, L. and Barth, Andreas (1996) "Vaccine Therapy for Malignant Melanoma" <i>CA-A Cancer Journal for Clinicians</i> 46, 4: 225-244.	
	B.10	Reinhold-Hurek, Barbara and Shub, David A. (1992) "Self-Splicing Introns in tRNA Genes of Widely Divergent Bacteria" <i>Nature</i> 357: 173-176.	
	B.11	Rosenberg, Steven A., <i>et al.</i> (1988) "Use of Tumor-Infiltrating Lymphocytes and Interleukin-2 In the Immunotherapy of Patients with Metastatic Melanoma" <i>The New England Journal of Medicine</i> 319, 25: 1676-1680.	
	B.12	Rovere, Patrizia <i>et al.</i> (1999) "Dendritic Cell Presentation of Antigens From Apoptotic Cells in a Proinflammatory Context" <i>Arthritis &amp; Rheumatism</i> 42, 7: 1412-1420.	

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PATENT AND TRADEMARK OFFICE

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet 4 of 4

Complete if Known

Application Number	10/ 263,330
Filing Date	October 2, 2002
First Named Inventor	FRANZOSO, Guido, <i>et al.</i>
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	21459-93823

B

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>		T <sup>2</sup>
	C.1	Scaffidi, Carsten <i>et al.</i> (1999) "Differential Modulation of Apoptosis Sensitivity in CD95 Type I and Type II Cells" <i>The Journal of Biological Chemistry</i> 274, 32: 22532-22538.	
	C.2	Stegh, Alexander H., <i>et al.</i> (2000) "Identification of the Cytolinker Plectin as a Major Early In Vivo Substrate for Caspase 8 During CD95- and Tumor Necrosis Factor Receptor-Mediated Apoptosis" <i>Molecular and Cellular Biology</i> 20, 15: 5665-5679.	
	C.3	Steinman, Ralph M., <i>et al.</i> (1999) "Antigen Capture, Processing, and Presentation by Dendritic Cells: Recent Cell Biological Studies" <i>Human Immunology</i> 60: 562-567.	
	C.4	Tatusova, Tatiana A., <i>et al.</i> (1999) "Complete Genomes in WWW Entrez: Data Representation and Analysis" <i>Bioinformatics</i> 15, 7/8: 536-543.	
	C.5	Van Antwerp, Daniel J., <i>et al.</i> (1996) "Suppression of TNF- $\alpha$ -Induced Apoptosis by NF- $\kappa$ B" <i>Science</i> 274 (5288): 787.	
	C.6	Vito, Pasquale <i>et al.</i> (1996) "Interfering With Apoptosis: Ca <sup>2+</sup> - Binding Protein ALG-2 and Alzheimer's Disease Gene ALG-3" <i>Science</i> 271 (5248): 521.	
	C.7	Wang, Xiantao <i>et al.</i> (1999) "gadd In not Required for Activation of c-Jun N-terminal Kinase or p38 During Acute Stress" <i>The Journal of Biological Chemistry</i> 274, 42: 29599-29602.	
	C.8	Yang, Jianfei <i>et al.</i> (2001) "IL-18-Stimulated GADD45 $\beta$ Required in Cytokine-induced, but not TCR-induced, IFN- $\gamma$ Production" <i>Nature Immunol</i> 2, 2: 157-164.	
	C.9		
	C.10		
	C.11		
	C.12		

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